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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,182	06/14/2006	David L. Kaplan	700355-053462	6154
50828	7590	04/01/2009	EXAMINER	
DAVID S. RESNICK NIXON PEABODY LLP 100 SUMMER STREET BOSTON, MA 02110-2131			SRIVASTAVA, KAILASH C	
			ART UNIT	PAPER NUMBER
			1657	
			NOTIFICATION DATE	DELIVERY MODE
			04/01/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

bostonpatent@nixonpeabody.com

mstembridge@nixonpeabody.com

Office Action Summary

Application No.

10/541,182

Applicant(s)

KAPLAN ET AL.

Examiner

Kailash C. Srivastava

Art Unit

1657

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2005 & 06/14/2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-39 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date: _____

DETAILED ACTION

1. The Preliminary amendments filed 30 June 2005 and on 14 June 2006 are acknowledged and entered.

Informal Matters

2. Please note that the correct Serial Number of your Non-Provisional Application (i.e., USSN) under prosecution at the United States Patent and Trademark Office (i.e., USPTO) is 10/541,182. Please ensure that the correct USSN (i.e., 10/541,182) for the instant Non-Provisional U.S. application is cited in all future correspondence with this Office.

3. The assigned Art Unit location for USSN 10/541,182 at the USPTO is 1657. To aid in correlating any papers for the instant application (i.e., USSN 10/541,182), all further correspondence regarding this application should be directed to Art Unit 1657.

4. The assigned Examiner to USSN 10/541,182 at the USPTO is Kailash C. Srivastava. To aid in correlating any papers for the instant application (i.e., USSN 10/541,182), all further correspondence regarding this application should be directed to Examiner Kailash C. Srivastava in Art Unit 1657.

Claims Status

5. Claims 40-59 have currently been cancelled.
6. Claim 12 has currently been amended.
7. Claims 1-39 are pending.

Election /Restriction

8. This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1 and 37 C.F.R. §1.475. Restriction to one of the following inventions is required under 35 U.S.C. §121 and §372.

In accordance with rules cited supra, applicant(s) is/are required, in reply to this Office Action, to select a single invention to which the claims must be restricted.

- Group I, consisting of claims 1-11 drawn to a composition.

- Group II consisting of Claims 12-28 drawn to a process to prepare a porous silk fibroin.
- Group III consisting of Claims 29-31 drawn to another composition comprising silk fibroin and a biocompatible polymer.
- Group IV consisting of Claim 32 drawn to a process to produce tissue engineered construct.
- Group V, consisting of claims 33-36 drawn to a method to prepare a cartilage tissue.
- Group VI, consisting of Claims 37-39 drawn to a process to produce bone tissue.

Inventions are Independent and Distinct

9. The inventions listed in Groups I-VI above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The patent rules under 37 C.F.R. §1.475 for Unity of Invention (Paragraphs (a), (b) and (c)) are cited below:

The inventions listed in Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The patent rules under §1.475 for Unity of Invention (Paragraphs (a), (b) and (c)) are cited below:

§1.475 Unity of Invention before the International Searching Authority, the International Preliminary Examining Authority and during the National Stage

- (a) An International and National Stage Application shall relate to one invention only, or to a group of inventions so linked as to form a general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as whole, makes over the prior art.
- (b) An International or a National stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:
 - (1) A product and a process specially adapted for the manufacture of said product; or
 - (2) A product and process of use of said product; or
 - (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

- (4) A process and an apparatus or means specifically designed for carrying out the said process; or
- (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

(c) If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.

The groups of invention fall within category [(2), a product and a method of use of said product].

10. The inventions listed as Groups I-VI *supra* do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

PCT Rule 13.2 does not provide for multiple compositions, or multiple methods of making a composition, or multiple methods of use of a composition within a single application. Thus, the first appearing composition is combined with a corresponding first method of making said composition (if applicable) and/ or use of said composition. However, the additional composition and method claims each constitute a separate inventive Group.

In addition to the requirement that a Group of inventions must belong to one of the specific categories provided by PCT Rule 13.2, the inventions in the category, e.g., as a composition and a method of use of said composition, must have a special technical feature that unites them. See Patent rules under 37 C.F.R. §1.475, where a special technical feature is a contribution OVER THE PRIOR ART.

The special technical feature of each of groups I-VI, A porous silk fibroin material, its structure, the rheological properties (e.g., compressive modulus) of said silk fibroin, strengthening of said silk fibroin through cross linking, and concept of applying said constructed silk material in the fields of foods, medicine, chemical industry and cosmetics as exemplified by its application in enzyme immobilization/ entrapping is well recognized in the pertinent art (See, e.g., Asakura, T. 1987 Translated Title: STRUCTURAL CHARACTERISTICS OF SILK FIBROIN AND ITS APPLICATION TO ENZYME FIXATION MATERIAL, Bioindustry, Volume 4, issue 11 Pages 36-44). Thus, the material, *per-se*, its manufacture, properties and its application are recognized facts in the pertinent prior art and therefore there is no special technical feature among the Group I-VI inventions. Since no special technical feature exists between the inventions of groups I-VI, there is no unity of invention.

The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because. Under PCT Rule 13.2, they lack the same, or corresponding special technical features for the following reasons: the material, *per-se* its manufacture, properties and its application are

already known in the prior art by e.g., Asakura, T. (1987 Translated Title: STRUCTURAL CHARACTERISTICS OF SILK FIBROIN AND ITS APPLICATION TO ENZYME FIXATION MATERIAL, Bioindustry, Volume 4, issue 11 Pages 36-44).

The expression, "special Technical Feature" refers to those features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. Thus, a feature found in the prior art can not be considered to be a special technical feature.

10. In accordance with 37 C.F.R. §1.499, applicant (S) is/are required, in response to this action, to elect a single invention to which the claims must be restricted.

Applicants is/are advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 C.F.R. §1.143).

Species Election

11. This application contains Claims directed to the following patentably distinct species:

- (1st) Different sources of silk fibroin from among: silk worm or *Bombyx mori* or spider or genetically engineered silk listed in Claims 15-18;
- (2nd) Particles are selected from one of the following: e.g., alkali metal, alkaline earth metal halide, phosphates, sulfates, sugar crystals, water soluble polymer microspheres, or protein microspheres listed in Claims 21-23;
- (3rd) Additive selected from biologically active compound or pharmaceutically active compound; cell growth factor, cytokine, peptide having an integrin binding sequence, porous silk fibroin, or biocompatible polymer as listed in Claims 21-30;
- (4th) The group of polyethylene oxide, polyethylene glycol, collagen, fibronectin, keratin, polyaspartic acid, polylysine, alginate, chitin, chitosan, hyaluronic acid, pectin, polycaprolactone, polylactic acid (i.e., PLA), polyglycolic acid (i.e., PGA), polyhydroxyalkanoates (i.e., PHAL), dextrans, polyanhydrides (i.e., PAN) PLA-PGA, polyorthoester, polyfumarate, among the biocompatible materials as listed in Claim 31;
- (5th) Producing a tissue engineered construct, or cartilaginous tissue or bone tissue as listed in each of Claims 32, 33, or 37;

- (6th) Conditions for said construct or tissue comprise: non-essential amino acids, ascorbic acid-2-phosphate, dexamethasone, insulin or TGF- β 1 as listed in Claims 34, 35, or 39; and
- (7th) Conditions for constructing bone tissue comprising the conditions: -glycerophosphate, ascorbic acid-2-phosphate, dexamethasone and BMP-2 as listed in Claims 38-39.

The non-taxonomic species listed *supra* are independent or distinct because claims to the different non-taxonomic species recite the mutually exclusive characteristics of such non-taxonomic species. In addition, these non-taxonomic species are not obvious variants of each other based on the current record.

Accordingly, the search for each of the above inventions is not co-extensive, particularly with regard to the literature search. This is because the inventive groups discussed above incorporate numerous components and numerous ingredients within each of the same, single invention. For example, to conduct a literature search for invention in Group V, i.e., a cartilaginous tissue that is constituted of different components/steps as outlined above, one would be searching for a total number of combinations that will be a factorial of at least 33 components encompassing all the steps and the components with each one of the components/ingredients up to ingredient number 1 (i.e. 33*32, 33*31, 33*30, 33*29, 33*28, 33*27, 33*26, 33*25, 33*24, 33*23, 33*22,----- 33*1). Thus, this group alone will exert an enormous search burden on the Examiner. Therefore, if the applicants elect invention of Groups I -VI above, applicants must also make election of species as appropriate by electing one single species from each of the following categories (i.e., one species from each category as appropriate):

- o For invention in Groups II
 - ♦ only one type of silk as listed in (1st) Category *supra*, and in Claims 12, 15-18;
 - ♦ Only one type of particles as listed in (2nd) Category *supra*, and in Claims 21-23; and
 - ♦ Only one type of material as listed in (3rd) Category *supra*, and in Claims 21-28.
- o For inventions in Group III
 - ♦ Only one type of material as listed in (3rd) Category *supra*, and in Claims 29-30; and
 - ♦ Only one type of material as listed in (4th) Category *supra*, and in Claim 31.
- o For invention in Group V
 - ♦ only one type of silk as listed in (1st) Category *supra*, and in Claims 12, 15-18;
 - ♦ Only one condition listed in (6th) Category *supra*, and in Claims 34-35.

- o For invention in Group VI
 - ♦ only one type of silk as listed in (1st) Category supra, and in Claims 12, 15-18;
 - ♦ Only one condition listed in (6th) Category supra, and in Claim 39; and
 - ♦ Only one condition listed in (7th) Category supra, and in Claims 38- 39.

12. Applicants are required under 35 U.S.C. §121 to elect a single disclosed species for prosecution on the merit to which the claims shall be restricted if no generic claim is finally held to be allowable.

There is an examination and search burden for the above-mentioned patentably distinct species due to their mutually exclusive characteristics. The species require a special field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely raise different non-prior art issues under 35 U.S.C. §101 and or 35 U.S.C. §112, first paragraph.

13. Applicants are advised that the reply to this requirement to be complete **must include** (i) **an election of a species to be examined among the species listed in categories (1st)-(7th) even though the requirement may be traversed** (37 C.F.R. §1.143) and (ii) **identification of the claims encompassing the elected species, including any claims subsequently added**. An argument that a claim is allowable, or that all claims are generic is considered non-responsive unless accompanied by an election.

The election of species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 C.F.R. §1.144. If claims are added after the election, applicant(s) must indicate which of these claims are readable on the elected species.

Should applicant(s) traverse on the ground that the species are not patentably distinct, applicant(s) should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103(a) of the other species. Upon the allowance of a generic claim, applicants will be entitled to

consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141.

In accordance with 37 C.F.R. § 1.499, applicants are required that a reply to this requirement must include an identification of the species that are listed in categories (1st)-(7th) and is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election of a Group and a corresponding species. If claims are added after the election, applicant must indicate which Claims are readable upon the elected species [M.P.E.P § 809.02(a)].

14. Applicants are reminded that upon the cancellation of claims to a non-elected invention and species, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(I).

15. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of M.P.E.P § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 C.F.R. § 1.116; amendments submitted after allowance are governed by 37 C.F.R. § 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 C.F.R. § 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. § 101, § 102, § 103, and § 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. § 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See M.P.E.P § 804.01.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner

can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Jon Weber can be reached at (571)-272-0925 Monday through Thursday 7:30 A.M. to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kailash C Srivastava/
Examiner, Art Unit 1657

Kailash C. Srivastava
Patent Examiner
Art Unit 1657
(571) 272-0923

22 March 2009
/David M. Naff/
Primary Examiner, Art Unit 1657